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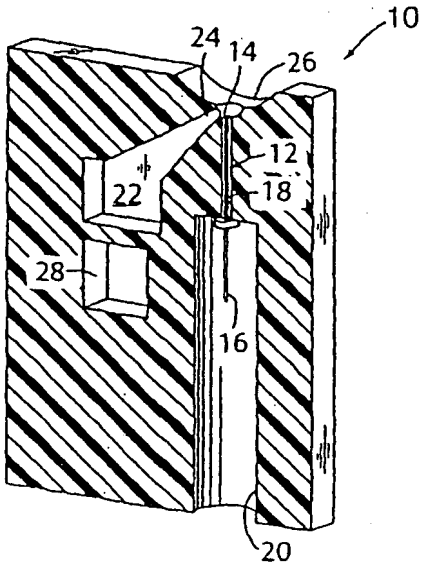
(54) Title: METHOD AND APPARATUS FOR LANCET LAUNCHING DEVICE INTEGRATED ONTO A BLOOD-SAMPLING CARTRIDGE




(57) Abstract: A method and apparatus for obtaining a sample of blood. An embodiment consists of an apparatus which integrates lancing, sample collection, and analysis. The presence of patients finger on the active sampling area can be sensed by monitoring the pressure applied by the finger on the device.

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# METHOD AND APPARATUS FOR LANCET LAUNCHING DEVICE INTEGRATED ONTO A BLOOD-SAMPLING CARTRIDGE

## TECHNICAL FIELD

Lancing devices are well known in the medical health-care products industry for piercing the skin to produce blood for analysis. Biochemical analysis of blood samples is a diagnostic tool for determining clinical information. Many point-of-care tests are performed using capillary whole blood, the most common being monitoring blood glucose level in diabetics. Typically, a drop of blood is obtained by making a small incision in the fingertip, creating a small wound, which generates a small blood droplet on the surface of the skin.

## BACKGROUND ART

Early methods of lancing included piercing or slicing the skin with a needle or razor. Current methods utilize lancet drivers that contain a multitude of spring, cam and mass actuators to drive the lancet. These include cantilever springs, diaphragms, coil springs, as well as gravity plumbs to actuate the lancet. Typically, the device is pre-cocked, or the user cocks the device. The device is held against the skin and the user mechanically triggers the ballistic launch of the lancet.

The problem with current devices is that they require two hands to operate, one to hold the device and push a button which activates the device, and the other hand to provide a finger for lancing. After lancing, the finger needs to be free to move to another device for collection of the blood droplet and subsequent analysis.

Generally, known methods of blood sampling require several steps. First, a measurement session is set up by gathering various paraphernalia such as lancets, launchers, test strips, instrument, etc. Second, the patient must assemble the paraphernalia by loading a sterile lancet, loading a test strip, and arming the launcher. Third, the patient must place their finger against the lancet launcher and using the other hand activate the launcher. Fourth, the patient must put down the launcher and place the bleeding finger against a test strip, which may or may not have been loaded into the instrument. The patient must insure blood has been loaded onto the test strip and the

instrument has been calibrated prior to such loading. Finally, the patient must dispose of all the blood contaminated paraphernalia including the lancet. What has been needed is a blood sampling device and method that simplifies the blood sampling procedure.

## DISCLOSURE OF INVENTION

Embodiments of the present invention are related to medical health-care products and to methods for obtaining blood for chemical analysis. More particularly, embodiments of the invention relate to devices and methods for piercing the skin (lancing) with a sensor to detect the presence of a patient's finger and activate the lancet automatically. In some embodiments, the cartridge and lancet are disposable.

In accordance with embodiments of the invention, a patient will be able to obtain a sample of blood in an ergonomic, convenient way using a method and apparatus which integrates lancing, sample collection, and analysis. The presence of patients finger on the ergonomic sampling area is sensed by monitoring the pressure applied by the finger on the cartridge which houses the lancet. The application of a predetermined pressure is measured by a piezoelectric or electrical circuit.

Advantages can be achieved in a blood sampling device by integrating the lancing and blood sample collection procedure so that the device can capture and transport the capillary blood from the wound created by the lancet to a desired active area, such as a strip for analyzing glucose. This can be done in embodiments of the invention by integrating the lancet, conduit and reservoir into a disposable cartridge which can be inserted into a hand-held sampling device with instrumentation for analyzing the blood sample.

In the use of an embodiment of the invention, a finger is placed over an ergonomically contoured sampling area and pressure is applied with the finger so that a sensor will activate the lancet, which will, in turn, lance the finger and allow the blood sample to be collected in the conduit and transported to the reservoir for analysis in a single step from the patient's perspective.

## BRIEF DESCRIPTION OF DRAWING

The objects, advantages and features of this invention will be more readily appreciated from the following detailed description, when read in conjunction with the accompanying drawing, in which:

Figure 1 is a drawing of the cartridge which houses the lancet.

Figure 2 is a drawing of the chamber in the sampling device where the cartridge is loaded.

Figure 3 is a drawing of the cartridge loaded into the sampling device.

Figure 4 is a drawing of an alternate lancet configuration.

Figure 5 is a drawing of the orifice and ergonomically contoured sampling area.

Figure 6 is a drawing of the lancing event.

## BEST MODE FOR CARRYING OUT THE INVENTION

Reference will now be made to embodiments of the invention, examples of which are illustrated in the accompanying drawings. Wherever possible, the same reference numbers will be used throughout the drawings to refer to the same or like parts.

Figure 1 shows the disposable cartridge (10) which houses the lancet (12). Disposable means that the cartridge is used for one lancing cycle and is then discarded. The lancet (12) has a distal end (16) which connects to the driver (40) and a proximal end (14) which lances the skin. The proximal end (14) is embedded within the conduit (18). Embedded means completely shielded by the cartridge when it is not lancing. The distal end (16) extends into the cavity (20). The reservoir (22) has a narrow opening (24) on the ergonomically contoured surface (26) which is adjacent to the proximal end (14) of the lancet (12). The term ergonomically contoured is generally defined to mean shaped to snugly fit a finger placed on the surface. The term reservoir is generally defined to mean an area which allows pooling of the blood sample. The term narrow is generally defined to mean a reduction in diameter of the reservoir so as to exploit capillary forces to better channel the blood into the rest of the reservoir. The term adjacent, as used in the context of the proximity of the proximal end (16) and narrow opening (24), is generally defined to mean that the proximal end (16) and the narrow opening (24) are located in the same general area. The cartridge (10) is capable of channeling the blood sample, which means transporting through small passages (not shown), to an active area (28) which corresponds to the device's system for analyzing

the blood. This system can consist of a chemical, physical, optical, electrical or other means of analyzing the blood sample. The lancet and reservoir embodiment illustrated are integrated into the cartridge in a single packaged unit.

Figure 2 shows the chamber (30) in the sampling device where the cartridge is loaded. The cartridge is loaded on a socket (32) suspended with springs (34) and sits in slot (36). The launcher (38) is attached to the socket (32). The launcher has a proximal end (40) and a distal end (42). The launcher is any mechanical (such as spring or cam driven) or electrical (such as electromagnetically or electronically driven) means for advancing, stopping, and retracting the lancet. There is a clearance (44) between the distal end of the launcher (42) and the sensor (46) which is attached to the chamber (30). The socket (32) also contains the system for analyzing the blood (48) which corresponds to the active area (28) on the cartridge (10) when it is loaded into the socket (32).

Figure 3 shows a cartridge (10) loaded into the socket (32). The active area (28) and system for analyzing the blood (48) overlap. The launcher (38) fits into the cavity (20). The proximal end (40) of the launcher (38) abuts the distal end (16) of the lancet (12). The patient's finger (50) sits on the ergonomically contoured surface (26).

Figure 4 shows a drawing of an alternate lancet configuration where the lancet (12) and launcher (38) are oriented to lance the side of the finger (50) as it sits on the ergonomically contoured surface (26).

Figure 5 illustrates with exploded detail the orifice (52) and ergonomically contoured surface (26). The conduit (18) has an orifice (52) which opens on a blood well (54). The narrow opening (24) of the reservoir (22) also opens on the blood well (54). The diameter of the narrow opening (24) is significantly greater than the diameter of the orifice (52) which is substantially the same diameter as the diameter of the lancet (12). After the lancet is retracted, the blood flowing from the finger (50) will collect in the blood well (54). The lancet (12) will have been retracted into the orifice (52) effectively blocking the passage of blood down the orifice (52). The blood will flow from the blood well (54) through the narrow opening (24) into the reservoir (22).

Figure 6 shows a drawing of the lancing event. The patient applies pressure by pushing down with the finger (50) on the ergonomically contoured surface (26). This applies downward pressure on the cartridge (10) which is loaded into the socket (32).

As the socket (32) is pushed downward it compresses the springs (34). The sensor (46) makes contact with the distal end (42) of the launcher (38) and thereby detects the presence of the finger on the ergonomically contoured surface. Detection means sensing using electrical means. The sensor is a piezoelectric device which detects this pressure and sends a signal to circuit (56) which actuates the launcher (38) and advances and then retracts the lancet (12) lancing the finger (50). In another embodiment, the sensor (46) is an electric contact which closes a circuit when it contacts the launcher (38) activating the launcher (38) to advance and retract the lancet (12) lancing the finger (50). Activating means beginning the lancing event, which consists of advancing, stopping, and retracting the lancet.

An embodiment of the invention is a method of sampling which reduces the number of steps that must be taken by a patient to obtain a sample and analysis of the sample. First, the patient loads a cartridge with an embedded sterile lancet into the device. Second, the patient initiates a lancing cycle by turning on the power to the device or by placing the finger to be lanced on the ergonomically contoured surface and pressing down. Initiation means arming the device. This initiation prompts the sensor. Prompting means that the sensor is made operational and given control to activate the launcher. Prompting is a safety precaution to avoid unintentionally launching the lancet. The sensor is unprompted when the lancet is retracted after its lancing cycle to avoid multiple lancing events that would cause unnecessary pain and obstruct the collection of the blood sample. The lancing cycle consists of arming, advancing, stopping and retracting the lancet, and collecting the blood sample in the reservoir. The cycle is complete once the blood sample has been collected in the reservoir. Third, the patient presses down on the cartridge which forces the launcher to make contact with the sensor and activates the launcher. The lancet then pierces the skin and the reservoir collects the blood sample. The patient is then optionally informed to remove the finger by an audible signal such as a buzzer or a beeper, and/or a visual signal such as an LED or a display screen. The patient can then dispose of all the contaminated parts by removing the cartridge and disposing of it. In another embodiment, multiple cartridges may be loaded into the sampling device in the form of a cassette. The patient is informed by the device as to when to dispose of the entire cassette after the analysis is complete.

Other embodiments of the invention will be apparent to those skilled in the art from consideration of the specification and practice of the invention disclosed herein. It is intended that the specification and examples be considered as exemplary only, with a true scope and spirit of the invention being indicated by the following claims.

## CLAIMS

1. A sampling device comprising:
a lancet for obtaining a blood sample from a user, said lancet having a distal end and a proximal end;
a reservoir for collecting the blood sample adjacent to the proximal end of said lancet;
a launcher attached to the distal end of said lancet; and
a sensor on said sampling device for detecting said user and initiating a lancing cycle.

2. A sampling device according to claim 1 wherein said device further comprises:
a system for analyzing the blood sample.

3. A sampling device according to claim 2 wherein:
said lancet and said reservoir are integrated into a disposable cartridge.

4. A sampling device according to claim 3 wherein:
said launcher contacts said sensor to detect said user and to activate said launcher.

5. A sampling device according to claim 4 wherein:
said sensor is prompted when said disposable cartridge is loaded into said device.

6. A sampling device according to claim 5 wherein:
said sensor is unprompted upon retraction of said lancet.

7. A sampling device according to claim 1 wherein:
said sensor comprises a piezoelectric sensor for detecting pressure applied by said user on said piezoelectric sensor.

8. A sampling device according to claim 1 wherein:
said sensor comprises an electric circuit which is closed when pressure is applied by said user on said sensor.

9. A sampling device comprising:
a disposable cartridge comprising a conduit, a reservoir for collecting a blood sample, said reservoir having a narrow opening on an ergonomically contoured surface of said cartridge;
a lancet for obtaining a blood sample from a finger, said lancet having a first distal end and a first proximal end, said lancet embedded within said conduit, said conduit running from a cavity within said cartridge to an orifice on said ergonomically contoured surface, said first proximal end used to pierce said finger, said lancet oriented so that the first distal end is longitudinal to the cavity, and the first proximal end is longitudinal to the orifice;
a launcher on said device fitted within said cavity, said launcher having a second proximal end and a second distal end; said second proximal end connecting to said first distal end; and
a sensor affixed to said device, said sensor adjacent to the second distal end, said sensor detecting said finger on the ergonomically contoured surface; said sensor initiating a lancing cycle.

10. A sampling device according to claim 9 wherein said device further comprises:

a system for analyzing the blood sample, by channeling blood from said reservoir to an active area within said cartridge, said active area overlapping said system.

11. A sampling device according to claim 9 wherein:
said sensor comprising a piezoelectric circuit, said circuit contacting the second distal end when the finger applies pressure on said ergonomically contoured surface.

12. A sampling device according to claim 9 wherein:
said sensor comprising an electric circuit, said circuit contacting the second distal end when the finger applies pressure on said ergonomically contoured surface.

13. A method of sampling comprising of the steps of:
loading a disposable cartridge with an embedded lancet into a lancing device;
placing a piece of skin on a surface of said cartridge;
initiating a lancing cycle by prompting a sensor on said lancing device;
activating a launcher;
lancing said skin to obtain a blood sample;
collecting said blood sample; and
disposing said cartridge.

14. A method of sampling according to claim 13 further comprising of the step of:
analyzing said blood sample.

15. A method of sampling according to claim 13 further comprising of the step of:
informing a user to remove said skin when said lancing cycle is complete.

16. A method of sampling according to claim 15 wherein:
informing said user further comprises giving an audible signal when said lancing cycle is complete.

17. A method of sampling according to claim 15 wherein:
informing said user further comprises giving a visual signal when said lancing cycle is complete.

18. A method of sampling according to claim 13 further comprising of the step of:
unprompting said sensor upon retraction of said lancet.

19. A method of sampling according to claim 13 wherein:
activating said launcher comprises applying pressure through said skin to said surface.

20. A method of sampling according to claim 19 wherein:
said skin is on a finger.

21. A method of sampling according to claim 20 wherein:
said surface is ergonomically contoured to said finger.

22. A method of sampling comprising of the steps of:
loading a disposable cartridge into a lancing device with a lancet embedded within a conduit which has an orifice on a surface of said cartridge;
initiating a lancing cycle by prompting a sensor on said lancing device;
activating said lancing cycle by having a patient place a finger over an ergonomically contoured area located on said surface such that said finger overlaps with said orifice;
lancing the finger to obtain a sample of blood;
collecting said sample of blood through said orifice;
informing said user to remove said finger from the ergonomically contoured active sampling area; and
transferring said cartridge for analysis.

23. A method of sampling comprising of the steps of:
loading a disposable cartridge with an embedded lancet into a lancing device;
initiating a lancing cycle and activating a sensor on said lancing device by placing a piece of skin on a surface of said cartridge;
lancing said skin to obtain a blood sample;
collecting said blood sample; and
transferring said cartridge for analysis.

24. A method of sampling according to claim 23 further comprising of the step of:
analyzing said blood sample.

25. A method of sampling according to claim 23 further comprising of the step of:
informing a user to remove said skin when said lancing cycle is complete.

26. A method of sampling according to claim 25 wherein:
informing said user further comprises giving an audible signal when said lancing cycle is complete.

27. A method of sampling according to claim 25 wherein:
informing said user further comprises giving a visual signal when said lancing cycle is complete.

28. A method of sampling according to claim 23 further comprising of the step of:
unprompting said sensor upon retraction of said lancet.

29. A method of sampling according to claim 23 wherein:
activating said launcher comprises applying pressure through said skin to said surface.

30. A method of sampling according to claim 29 wherein:
said skin is on a finger.

31. A method of sampling according to claim 30 wherein:
said surface is ergonomically contoured to said finger.

32. A method of sampling comprising of the steps of:
loading a disposable cartridge with a lancet embedded within a conduit that has an orifice on a surface of said cartridge;
initiating and activating a lancing cycle by having a patient place a finger over an ergonomically contoured area located on said surface such that said finger overlaps with said orifice;

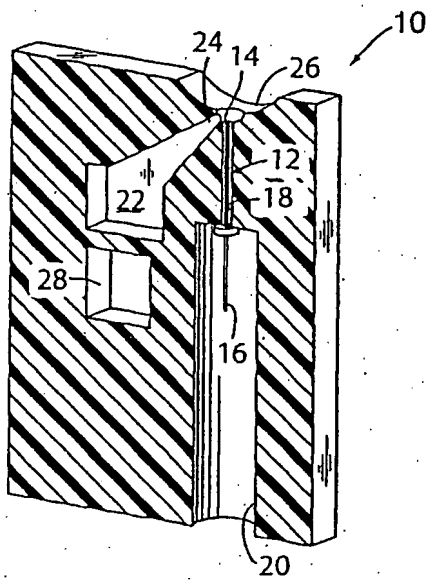
lancing the finger to obtain a sample of blood;

collecting said sample of blood;

informing said user to remove said finger from the ergonomically contoured active sampling area; and

transferring said cartridge for analysis.

Figure 1



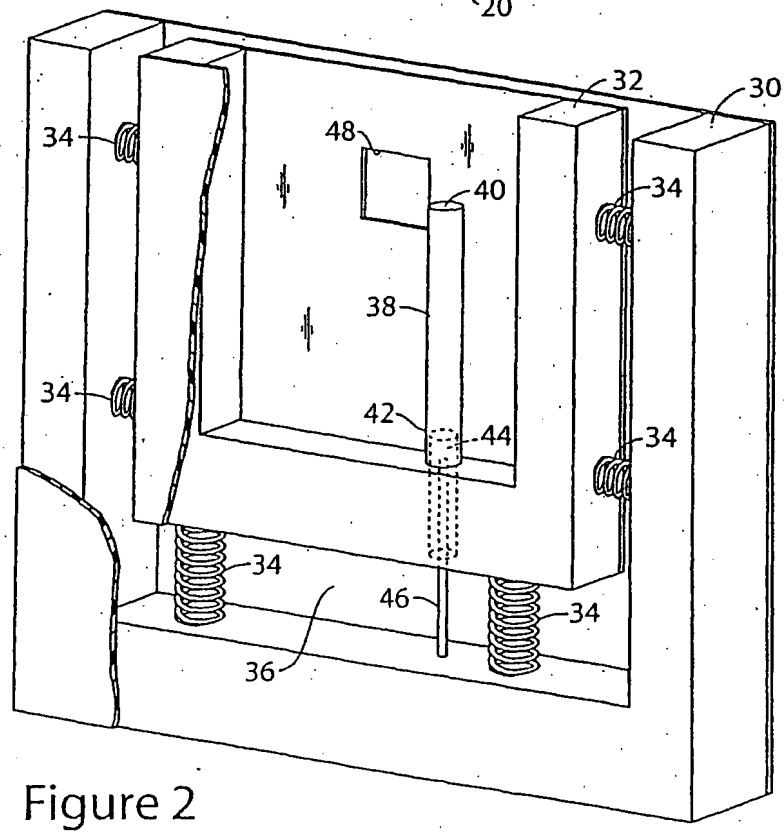




Figure 2

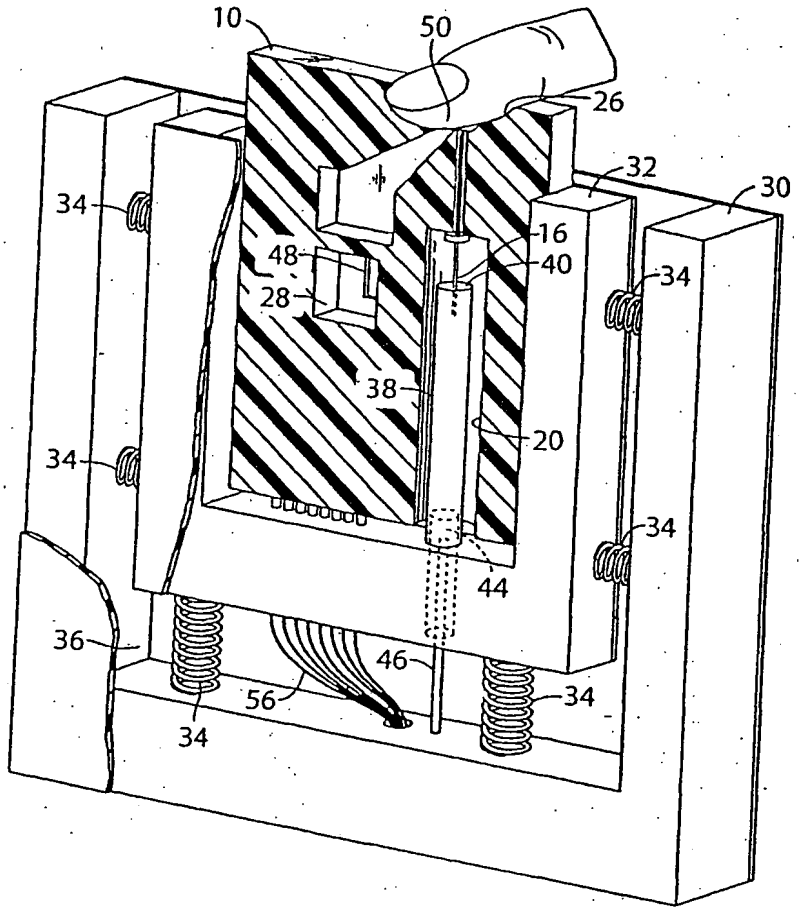



Figure 3

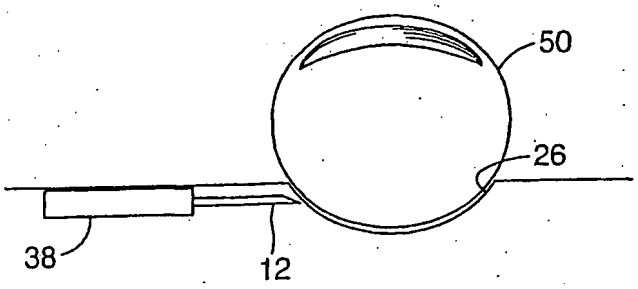



Figure 4

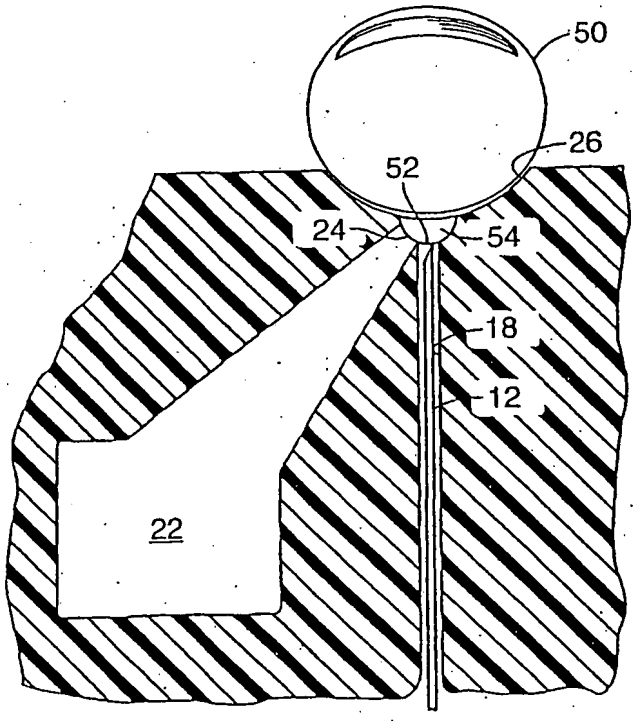



Figure 5

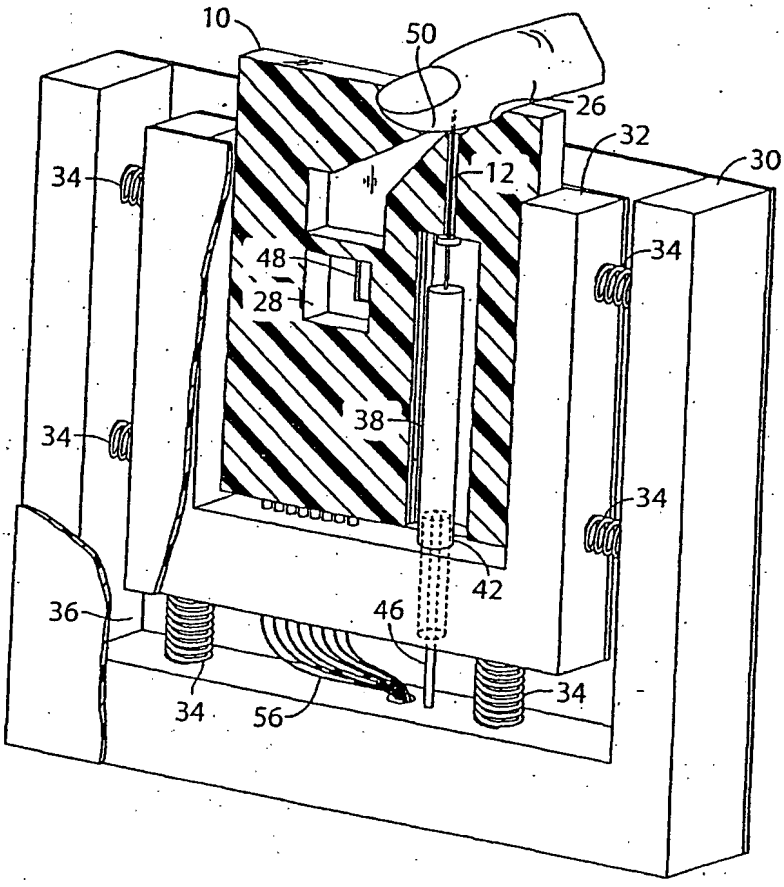



Figure 6